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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,827

12/09/2003

Thomas A. Alheidt

P-6101P1

4380

26253

7590

09/06/2005

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAM

Office Action Summary	Application No. 10/731,827	Applicant(s) ALHEIDT ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/9/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 3/28/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Copies of WO 95/28978 and WO 98/56440 have not been submitted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2,4-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimard (USPN 5,795,337) or Grimard et al (USPN 5,899,881). Grimard discloses a barrel and a plunger. The plunger is attached to the distal end of the stopper (20/200) when the fluid is being injected. See figures 5 and 11-12, respectively. The device also includes anti-reflux means (see below) and a projection (29/250). Anti-reflux means includes the conical portion of the stopper having an angle of about 110 degrees and a conical shaped distal wall (see figures 6 and 11-12, respectively). The chamber includes flush solution 46/"F". The stopper is made from a thermoplastic elastomer. The syringe has a needle and a cavity. See figures 6 and 6-12,

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respectively. For the method steps, see 1:64-2:21 and 8:62-11:67, respectively. It is considered inherent that the syringe will be sterilized and contained in protective packaging since the device is disclosed for human use.

Grimard meets the claim limitations as described above but fails to include the method of providing a plurality of barrels, providing a plurality of stoppers and selecting a stopper and a barrel.

However, at the time of the invention it would have been obvious by one skilled in the art to provide a plurality of barrels and a plurality of stoppers and to select one stopper and one barrel and to insert the one stopper in the one barrel. These steps would obviously occur if one decided to make at least two syringes for use. In order to make two syringes, one would need to provide two barrels and two stoppers. Then one would obviously select one of the barrels and one of the stoppers and insert the first stopper into the first barrel. Finally, one would select the remaining barrel and stopper in order to make the second syringe.

Claims 3,6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grimard in view of Caizza et al (USPN 5,807,374) or Odell et al (USPN 6,361,524). Grimard meets the claim limitations as described above but fails to include providing a tip cap and the method of introducing the therapeutic into an IV catheter with a sealing valve.

However, both Caizza and Odell teach caps for maintaining the sterility of the syringe before use and during transport. One skilled in the art would have incorporated the cap into the invention of Grimard in order to maintain the sterility of the contents of the syringe prior to use thereby enhancing the safety of the patient from infection.

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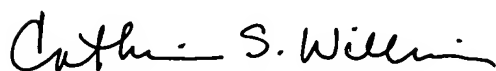
Additionally, one would have incorporated the IV catheter and sealing valve of either reference into the invention of Grimard. The IV seal is a mechanism for less invasive repeat injections into a patient and would have been incorporated in order to not have to repeatedly puncture the patient with a needle stick.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams
September 1, 2005